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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,131

Applicant(s)

MAYE, JOHN P.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/5/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1-5 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1, as drafted in its entirety, are rendered vague and indefinite because it is uncertain as to whether the subject matter of the instantly claimed invention is drawn to a method of making an organic food supplement for livestock or a method of orally administering or "delivering" an organic food supplement to livestock. Furthermore, the metes and bounds of the claims are rendered vague and indefinite because the subject matter of Claim 1 has not been properly construed by terms that limit its scope. For instance, the metes and bounds of Claim 1 are rendered vague and indefinite by the phrase "delivering the hops for oral ingestion" because it is unclear as to what or to whom the hop acids are delivered.

Also, the metes and bounds of Claim 1 are rendered vague and indefinite by the phrase, "to inhibit certain types of undesirable bacteria commonly found in the digestive systems of livestock", because it is uncertain as to what "certain types" of bacteria commonly found in the digestive systems of livestock Applicant considers as "undesirable". The lack of clarity renders the claim ambiguous.

Claim 1 recites the limitation "the digestive systems of livestock" in line 4. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting "the" from the limitation.

Given the foregoing, Claim 1, as drafted, is generally unsearchable because it is uncertain as to the subject matter Applicant intends to direct the invention. Thus, a proper search of the claim, as well as the claims depending therefrom, as drafted, is precluded because an initial analysis of the claims by the Examiner finds that the boundaries of the protection sought by Applicant cannot be identified and its not understood how the claims relate to and define what Applicant has indicated is the invention. Hence, Claim 1, as well as Claims 2-5 and 12, as drafted, fails to satisfy the requirement of 35 U.S.C. 112, second paragraph, that the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which Applicant regards as his or her invention. However, for the purposes of examination and for the purpose of expeditious prosecution of the instant application, the claims have been interpreted as reading on a method of "preparing" an organic food supplement for livestock for oral ingestion by mixing the acids with a livestock feed, wherein the hop acids are mixed with the feed in an amount to inhibit certain types of undesirable bacteria commonly found in digestive systems of livestock, given that the positive statement included in the drafting of the limitations of Claim 1 recite "delivering the hop acids for oral ingestion by mixing the acids with a livestock feed"; and, given that the recitation of "using hop acids as an organic food supplement for livestock" fails to fully define the scope of the instantly claimed invention.

The metes and bounds of Claims 1, 2, 6, 10 and 12-14-7 are uncertain because it is unclear as to the identification of the ingredient, namely "hop", to which Applicant intends to direct the subject matter. Although the use of common names or

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traditional/ethnopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical matter noted in this application. Applicant may overcome the rejection by replacing "hop" with Humulus lupulus (hop).

Claim 4, line 2, is rendered indefinite by the term, "adlupulone f" because the term is not recognized in the art. At present, the claim is unsearchable with regard to this term as no beta acid compound with the prescribed name was found searchable. It appears that the term "adlupulone f" is a typographical error or misspelling of adlupulone. Appropriate correction is required, if the assumption is true. If not, the Examiner's preliminary analysis and search demonstrates that the claimed subject matter cannot be adequately searched by class or keyword among patents and typical sources of non-patent literature.

Claim 5 recites the limitation "the amount of hop acid" in line 1. There is a lack of clear antecedent basis for this limitation in the claim.

The metes and bounds of Claim 13, line 5, are rendered vague and indefinite by the phrase, "inhibiting certain types of undesirable bacteria commonly found in the digestive systems of livestock", because it is uncertain as to what "certain types" of bacteria commonly found in the digestive systems of livestock Applicant considers as "undesirable". The lack of clarity renders the claim ambiguous.

The metes and bounds of Claim 12, as drafted in its entirety, are rendered vague and indefinite because it is uncertain as to the subject to which Applicant intends to

direct the instantly claimed invention. For instance, it is unclear as to what is the identity or as to what type of hop acid corresponds to a "hop acid capable of increasing the level of propionate in the digestive system fluid". Moreover, it is unclear as to what or to whom the administering of the "hop acid capable of increasing the level of propionate in the digestive system fluid" is performed because Claim 1 does not recite an indirect object to which an organic food supplement is administered or delivered.

Claim 12 recites the limitation "the hop acid capable of increasing the level of propionate in the digestive system" in line 1 to line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the level of propionate" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the digestive system fluid" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the digestive systems of livestock" in line 5. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting "the" from the limitation.

Claims 5, 10 and 14 recite the abbreviation "ppm". Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter. Applicant may overcome the rejection by replacing "ppm" with parts per million (ppm).

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All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. In the instant case, the claim fails to further limit the subject matter of Claim 1 because the phrase, "wherein the amount of hop acid is 2 ppm of digestive system fluid", does not further define the claim-designated method for preparing an organic food supplement for livestock comprising delivering the hop acids for oral ingestion by mixing the acids with a livestock feed. In other words, the subject matter of Claim 5 is directed to the amount of hop acid present in digestive system fluid instead of the amount of hop acid present in the organic food supplement for livestock. Moreover, the Office notes that nowhere in the recitation of Claim 1, as presently drafted, is there any mention of "digestive system fluid".

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. In the instant case, the claim fails to further the limit the subject matter of Claim 1 because the subject matter of Claim 1

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appears to be directed to a method of preparing an organic food supplement, whereas the subject matter of Claim 12 appears to be directed to a "process step" of administering a hop acid capable of increasing the level of propionate in the digestive system fluid. The Office notes that nowhere in the recitation of Claim 1, as presently drafted, is there any mention of any type or kind of "hop acid" having the claimed functional effect to increase the level of propionate in the digestive system.

Claim 14 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. In the instant case, the claim fails to further limit the subject matter of Claim 13 because the phrase, "wherein the effective amount of hop acid is from 1 ppm to about 30 ppm of digestive system fluid", does not further define the claim-designated method for preparing an organic food supplement for livestock comprising delivering the hop acids for oral ingestion by mixing the acids with a livestock feed. In other words, the subject matter of Claim 14 is directed to the amount of hop acid present in digestive system fluid instead of the amount of hop acid present in the claim-designated animal feed. Moreover, the Office notes that nowhere in the recitation of Claim 13, as presently drafted, is there any mention of "digestive system fluid".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinemann (B*), as evidenced by the teachings of Kurhts (C*), Owades (D*) and Murtaugh et al. (E*). As discussed above, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

Applicant claims a method of using hop acids as an organic food supplement for livestock comprising delivering the hop acids for oral ingestion by mixing the acids with a livestock feed, wherein the hop acids are mixed with the feed in an amount to inhibit certain types of undesirable bacteria commonly found in the digestive systems of livestock. Applicant further claims the method of claim 1 wherein the hop acids as well as their corresponding salts are selected from at least one of the group consisting of alpha acids, beta acids, isoalpha acids, rho-isoalpha acids, tetrahydroisoalpha acids and hexahydroisoalpha acids. Applicant further claims the method of claim 2 wherein the alpha acids are selected from at least one of the group consisting of humulone, cohumulone, and adhumulone. Applicant further claims the method of claim 2 wherein the beta acids are selected from at least one of the group consisting of lupulone,

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colupulone, and adlupulone f. Applicant further claims the method of claim 1 wherein the amount of hop acid is 2 ppm of digestive system fluid. Applicant further claims the method of claim 1 further comprising administering the hop acid capable of increasing the level of propionate in the digestive system fluid.

Applicant claims an animal feed comprising a feed plant selected from at least one of the group consisting of corn, barley, alfalfa, wheat, and sorghum, and an effective amount of hop acid capable of inhibiting certain types of undesirable bacteria commonly found in the digestive systems of livestock. Applicant further claims the animal feed of claim 13 wherein the effective amount of hop acid is from about 1 ppm to about 30 ppm of digestive system fluid of the livestock.

Heinemann teaches an organic food supplement comprising an infusion of hop flowers and barley. The composition taught by Heinemann is prepared by mixing semi-germinated barley grain in an infusion of hop flowers, and drying the mixture until the contents of water agrees approximately with that of the natural grain. Heinemann does not expressly teach that the reference composition comprises hop acids. However, as made evident by the teachings of Kurhts, Owades and Murtaugh, it is well known in the art of chemistry and botany that alpha-acids, e.g., humulone, cohumulone and adhumulone, and beta-acids, e.g., lupulone, colupulone and adlupulone are inherent to hops, which are flowers of *Humulus lupulus* in the form of cones. Moreover, Kurhts teaches that hop acids exhibit antimicrobial activity. Therefore, absent evidence to the contrary, the claim-designated hop acids are inherent to the composition taught by Heinemann.

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It is also noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Moreover, there are no ingredients contained in the composition taught by Heinemann to preclude the use of the reference composition as an organic food supplement for livestock.

Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

The reference anticipates the claimed subject matter.

1-5 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Feil (N), as evidenced by the teachings of Kurhts (C*), Owades (D*) and Murtaugh et al. (E*). As discussed above, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

Applicant's claimed invention was set forth above.

Feil teaches a composition comprising barley, malt, hops, vitamin b and a little alcohol.

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Feil does not expressly teach that the reference composition comprises hop acids. However, as made evident by the teachings of Kurhts, Owades and Murtaugh, it is well known in the art of chemistry and botany that alpha-acids, e.g., humulone, cohumulone and adhumulone, and beta-acids, e.g., lupulone, colupulone and adlupulone are inherent to hops, which are flowers of *Humulus lupulus* in the form of cones. Moreover, Kurhts teaches that hop acids exhibit antimicrobial activity. Therefore, absent evidence to the contrary, the claim-designated hop acids are inherent to the composition taught by Heinemann.

It is also noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Moreover, there are no ingredients contained in the composition taught by Feil to preclude the use of the reference composition as an organic food supplement for livestock

Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

The reference anticipates the claimed subject matter.

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Claims 1, 2, 5 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Papadopoulou et al. (U). As discussed above, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

Applicant's claimed invention was set forth above.

Papadopoulou teaches a composition comprising barley and hop beta-acid, wherein the hop-beta acid used was at the levels of 1 ppm and 10 ppm of barley, on page 184, Column 2, first line of second paragraph. Papadopoulou further teaches a composition comprising 10 ppm of hop beta acid and barley composition was effective in eliminating the growth of *Escherichia coli*, yeast and fungi. On page 184, Column 1, second paragraph in its entirety, bridging Column 2, Papadopoulou teaches, "It is well recognized that hop compounds possess antimicrobial properties and these are now being used as preservatives [citations omitted]. The addition of 1 ppm of α -acid during steeping, or at cast, eliminated *Chromobacterium*, *Clavibacterium* and fungi."

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Moreover, there are no ingredients

contained in the composition taught by Papadopoulou to preclude the use of the reference composition as an organic food supplement for livestock. The reference anticipates the claimed subject matter.

Claims 1-5 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Egorova (BG, RU 2075298 C1), as evidenced by the teachings of Kurhts (C*), Owades (D*), Murtaugh et al. (E*) and Mannering et al. (V). As discussed above, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

Applicant's claimed invention was set forth above.

Egorova teaches the instantly claimed method of preparing an organic food supplement for livestock comprising mixing the claim-designated ingredients, and an animal feed thereof. For instance, Egorova teaches, "Addition of beer yeast autolysate (I), edible chalk (II) and common salt (III) to the mixture for producing farm animal feed, improves it quality. The mixture contains (wt. %): beer grains 82.8, malt shoots 7.5, grain waste 6, barley floats 0.7, aspirating and polishing waste 0.5, beer yeast 0.5, protein sediment 0.3, hop grains 0.2, (I) 0.2. content of 10-12%, ground to 0.5-3mm particle size, sieved and granulated".

Egorova does not expressly teach that the reference composition comprises hop acids. However, as made evident by the teachings of Kurhts, Owades and Murtaugh, it is well known in the art of chemistry and botany that alpha-acids, *e.g.*, humulone, cohumulone and adhumulone, and beta-acids, *e.g.*, lupulone, colupulone and

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adlupulone are inherent to hops, which are flowers of *Humulus lupulus* in the form of cones. Moreover, Kurhts teaches that hop acids exhibit antimicrobial activity. Included also in the mixture used in the animal feed from beer production taught by Egorova is beer yeast. As made evident by the teachings of Mannering, both alpha acids and beta alphas are inherent to the brewer's (beer) yeast used in the animal feed taught by Egorova. See page 312, third paragraph, wherein Mannering teaches, "... (b) β -acids are known to be absorbed on brewer's yeast during the brewing process; (c) solvent fractionation of brewer's yeast showed the active component(s) to be lipid-soluble, weak acids, which have physical properties consistent with those of α - and β -acids." See Figure 1, wherein Mannering depicts the structures of the humulones and lupulones. Also, see page 321, third paragraph, first line, wherein Mannering teaches that hop components are unwittingly introduced into animal feeds, such as laboratory chows. Therefore, absent evidence to the contrary, the claim-designated hop acids are inherent to the composition taught by Egorova.

It is also noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Moreover, there are no

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ingredients contained in the composition taught by Egorova to preclude the use of the reference composition as an organic food supplement for livestock.

Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

The reference anticipates the claimed subject matter.

Claims 1-5 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. (F*), as evidenced by the teachings of Kurhts (C*), Owades (D*), Murtaugh et al. (E*), Mannering et al. (V) and Miller et al. (BG, GB 2072657 A). As discussed above, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

Applicant's claimed invention was set forth above.

Thompson teaches the instantly claimed inventions. For instance, Thompson teaches a method of preventing the development of liver abscesses in cattle fed on rations containing at least about 75 percent of high energy concentrates selected from the group consisting of corn, grain sorghums, wheat, barley, and molasses having a minimum net energy value of about 1.6 M. Cal./Kg by adding from about 5 percent to about 20 percent dried brewers grains containing spent hops to the ration as an additional source of crude fiber and protein and feeding the ration to the cattle.

Thompson teaches that the method of treatment is useful in the prophylaxis of liver

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abscesses resulting from undesirable bacteria commonly found in the digestive system of livestock, such as streptococci, staphylococci and corynebacteria, and particularly the organism *Spherophorus necrophorus*. Column 1, line 1 to Column 2, line 13. In Table IV, at Column 5-6, Thompson teaches an organic food supplement for livestock comprising a mixture of cracked corn (77.55%) and dried brewers grain with yeast (15%) and having a net energy value of 1.70 M Cal/Kg.

Thompson does not expressly teach that the reference composition comprises hop acids *per se*. However, included also in the mixture used in the animal feed from beer production taught by Thompson is beer yeast, as well as dried brewers grains containing spent hop. As made evident by the teachings of Mannering, both alpha acids and beta alphas are inherent to the brewer's (beer) yeast used in the animal feed taught by Thompson. See page 312, third paragraph, wherein Mannering teaches, "... (b) β -acids are known to be absorbed on brewer's yeast during the brewing process; (c) solvent fractionation of brewer's yeast showed the active component(s) to be lipid-soluble, weak acids, which have physical properties consistent with those of α - and β -acids." See Figure 1, wherein Mannering depicts the structures of the humulones and lupulones. Also, see page 321, third paragraph, first line, wherein Mannering teaches that hop components are unwittingly introduced into animal feeds, such as laboratory chows. Moreover, Miller teaches lupulones or beta-acids are inherent to spent hops, on page 1, Column 1, lines 43-54. Therefore, absent evidence to the contrary, the claim-designated hop acids are inherent to the composition taught by Thompson.

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It is also noted that the reference does not teach that the composition can be used in the manner instantly claimed, namely increasing the level of propionate in the digestive system fluid. However, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition, given that the ingredients comprising the composition taught by Thompson are one and the same or essentially the same as composition and method of making thereof disclosed by Applicant. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Moreover, there are no ingredients contained in the composition taught by Thompson to preclude the use of the reference composition as an organic food supplement for livestock.

Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 12-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thompson et al, (F*) in view of Schmalreck et al. (X), Lewis et al. (W), Chin et al. (U1), Haas et al. (AC, US 6,423,317 B1), Barney et al. (G), Nutter et al. (I*, US 5,827,895), and Nutter et al. (6,313,178 B1) and Johnson et al. (H*), and further in view of Mannering et al. (V) and Miller et al. (BG, GB 2072657 A). As discussed above, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

Applicant's claimed invention was set forth above.

The anticipatory teachings of Thompson are set forth above.

The claims are drawn to a method of using hop acids as an organic food supplement for livestock comprising delivering the hop acids for oral ingestion by mixing the acids with a livestock feed, wherein the hop acids are mixed with the feed in an amount to inhibit certain types of undesirable bacteria commonly found in the digestive systems of livestock. The claims are drawn to an animal feed comprising a feed plant selected from at least one of the group consisting of corn, barley, alfalfa, wheat, and sorghum, and an effective amount of hop acid capable of inhibiting certain types of undesirable bacteria commonly found in the digestive systems of livestock. Applicant further claims the animal feed of claim 13 wherein the effective amount of hop acid is from about 1 ppm to about 30 ppm of digestive system fluid of the livestock.

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Thompson does not expressly teach that the reference composition comprises hop acids *per se*. However, included also in the mixture used in the animal feed from beer production taught by Thompson is beer yeast, as well as dried brewers grains containing spent hop. However, it is well known in the art of chemistry that both alpha acids and beta alphas are inherent to the brewer's (beer) yeast used in the animal feed taught by Thompson as made evident by the teachings of Mannering (see page 312, third paragraph). Additionally, it is well known in the art of chemistry that hop acids are inherent to spent hops as made evident to the teachings of Miller (see page 1, Column 1, lines 43-54).

The cited reference discloses a method and an animal feed - - which appear to be identical to the presently claimed inventions since the ingredients used in the making of the reference composition, the method of preparing the product, and the functional effect of the product thereof to inhibit certain types of undesirable bacteria commonly found in the digestive systems of livestock are one the same or essentially the same as instantly claimed by Applicant. Thus, it would appear that the instantly claimed inventions are inherent to the teachings of Thompson, especially given that Mannering teaches that hop acids are inherent to brewers yeast; and, especially given that Miller teaches that hop acids are inherent to spent hops. Given the foregoing, the reference is considered to anticipate the claimed inventions.

Even if the claimed method and claimed product are not identical to the teachings of Thompson with regard to some unidentified characteristics, the difference between that which is disclosed and that which is claimed are considered to be so slight

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that the referenced method and reference animal feed are likely to inherently possess the same characteristics of the instantly claimed inventions particularly in view of the similar ingredients and functional effect they have been shown to share. In the alternative, even if the claimed method of using hop acids and claimed product differ from the reference method and reference composition by some unknown factor, such as any of the claim-designated hop acids recited in the Markush group of either Claims 2 or Claim 3, the instantly claimed invention still would have been obvious to one of ordinary skill in the art within the meaning of 35 U.S.C. 103. For instance, it would have been obvious to one ordinary skill in the art to add the claim-designated ingredients to the method of making the composition used in treatment taught by Thompson and the animal feed thereof to provide the instantly claimed invention because at the time the invention was made it was well known in the art of science that alpha acids, beta acids, isoalpha acids, rho-isoalpha acids, tetrahydroisoalpha acids and hexahydroisoalpha acids have the claim functional effect to inhibit certain types of undesirable bacteria commonly found in the digestive system of livestock, as evidenced by the teachings of Schmalreck, Lewis and Chin. For instance, both Schmalreck and Lewis teach the antimicrobial activities of lupulones and humulones against undesirable microorganisms often found as inhabitants of the digestive system of livestock intended for commercial production of food and dairy products for human consumption. For example, in Table 2 on page 209, Schmalreck shows the inhibitory activities of 4-deoxytetrahydro-cohumulone, isocohumulone, isohumulone and humulone against growth of *Bacillus subtilis*, *Micrococcus lysodeikticus*, *Staphylococcus aureus*, *Mycobacterium phlei*,

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Streptomyces viridans, *Saccharomyces cerevisiae* and *Pseudomonas fluorescens*. In Table 1, on page 918, Lewis shows the antibiotic spectra of humulone and lupulone against gram-positive bacteria, acid-fast bacteria, and Actinomycetes. On page 918, lines 3-20, Lewis further teaches that both humulone and lupulone at very low concentrations (about 1 ppm to about 12 ppm) inhibited acid production by a strain of *Lactobacillus bulgaricus*, inhibited the growth of both *Staphylococcus aureus* and *Bacillus mesentericus*, and inhibited the germination of spores of *Bacillus subtilis*. As reported by Lewis in Column 1 of page 916, Chin demonstrates that the oral administration of effective amounts of lupulone inhibits the growth of a virulent strain of *Mycobacterium tuberculosis* without toxicity. At the time the invention was made, it also would have been obvious to add the claim-designated ingredients to the teachings of Thompson to provide the instantly claimed inventions because each of the claim-designated hop acids recited in the Markush groups of Claim 2 and Claim 3 were known in the art for their beneficial functional effect. Firstly, Haas teaches a method of killing protozoa, e.g., ciliates or flagellates, comprising contacting the protozoa with an effective amount of alpha resin (about 100 to about 500 µg/ml) represented by humulone, cohumulone, adhumulone, prehumulone, and posthumulone, and its derivatives of isoalpha resin (xanthohumol) and tetra isoalpha resin; and/or an effective amount of beta resin (about 0.1 to about 2.0µg/ml) represented by lupulone, colupulone, adlupulone and prelupulone. Haas demonstrates the anti-protozoal activity of the alpha-acid containing alpha resins and beta-acid containing resins against *Paramecium caudatum*, *Euglena sp.*, *Tetrahymena pyriformis*, *Polytomella papillata*, *Amoeba*

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proteus and *Chaos sp.* Secondly, Barney teaches a method of inhibiting *Listeria* in a medium comprising administering an effective and save amount of tetrahydroisohumulone (8 ppm to 16 ppm) or hexahydrocolupulone (0.4 ppm to 1.6 ppm) or mixtures or salts thereof. The anti-listerial compounds taught by Barney can be incorporated directly into both liquid and solid foods (meat and poultry) to inhibit the growth of *Listeria* on the surface of foods, or to inhibit the *Listeria* that may be present in or may later enter or come in contact with a medium. Thirdly, Nutter ('895) teaches a method of inhibiting bacterial cell growth of drug resistant *Staphylococcus aureus* or drug resistant *Mycobacterium tuberculosis* in a mammal comprising orally administering an effect amount of hydrogenated lupulones including hexahydrolupulone, hexahydrocolupulone and hexahydroadlupulone. See Column 6, lines 62-67, wherein Nutter teaches the dose amounts of the hop acid compounds required to provide a therapeutic effect. Nutter further teaches that the compounds have been found to have anti-cancer and anti-leishmanial activities. In another instance, Nutter ('178) teaches a therapeutic method for inhibiting the growth of *Mycobacterium avium*-complex in a mammal comprising administering, including the oral route, an effective amount of the immediately mentioned hydrogenated lupulones. Finally, Johnson teaches a process of applying hop extract or the components of a hop extract containing a mixture of alpha acids, beta acids, and deoxy alpha acids to a food product to inhibit the growth of *Clostridium botulinum* in the food product; and a food product thereof including about 1 ppm or greater of a hop extract or hop extract components (5-100 ppm hop extract; 65% beta resins). Johnson also teaches a food product comprising hop extract wherein

the food product delivers about 1 ppm or greater of hop extract or the hop extract components to the stomach or intestine to prevent the growth of *Clostridium difficile*. Moreover, Johnson teaches that the reference method of applying effective amounts of the hop extract or hop acid components to a food product is useful in the inhibition of *Helicobacter pylori* in the stomach or intestine. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add, in the event that it was even necessary, any of the claim-designated hop acids to the animal feed and the method of use thereof taught by Thompson to provide the instantly claimed inventions because both Schmalreck and Lewis taught that effective amounts of hop acids exert antibacterial activity against undesirable organisms commonly found in the digestive systems of livestock; furthermore, Lewis taught not only the antibacterial activity of humulone and lupulone but also that they possess a lower order of antibiotic activity against of plant pathogenic fungi, on page 918, Column 2, lines 3-20; Chin taught that oral administration of an effective amount of lupulone (1500 mg per kilo) to experimental animal models suppressed the development of tuberculosis and exerted tuberculostatic effect *in vivo*; Haas demonstrated the antiprotozoal effect of alpha acids and beta acids against protozoa that lead to human diseases, and others that are pathogenic in the intestinal tract of mammals; Barney taught that hexahydrocolupulones and tetrahydroisohumulones can be incorporated into solid foods at very low concentrations to inhibit the growth or transfer of *Listeria* in a medium, such as a food product; Nutter ('895) taught that hydrogenated lupulones are useful in the making of therapeutic

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compositions to inhibit not only bacterial cell growth of drug resistant staphylococci and drug resistant mycobacteria but that they are also useful for making pharmaceuticals to inhibit cancer cell growth and bacterial cell growth of *Leishmania tarentolae*; Nutter ('178) also taught that the oral administration of effective amounts of hydrogenated lupulones to mammals beneficially inhibits the growth of *Mycobacterium avium* complex in mammals; and, lastly Johnson taught a process of making a food product for oral ingestion by a mammal comprising apply hop acids to the food product wherein the food product delivers about 1 pp or greater of the hop acids in the stomach or the intestine to prevent growth of *Clostridium difficile* and *Helicobacter pylori*; and, moreover, Johnson taught that the hop acid treated food products could be used to prevent the transmission of these known toxicogenic organisms which are well recognized in the art of microbiology as food pathogens inhabiting the digestive system fluid of livestock and implicated as the causative agent of food poisoning in humans, and other intoxications and infections in humans and/or livestock; and, Thompson suggested that his method of preventing liver abscesses comprising feeding cattle with the reference composition may be due to the presence of dried brewers yeast, spent hops and fiber therein: "The therapeutic effect may be due to better quality fiber content of dried brewers grains as compared with other sources of roughage. As dried brewers grains has a low spent hop content, it also is possible that a residual hop antiseptic action may be inhibiting the growth of the *S. necrophorus* organisms. The combination of the fiber in dried brewers grains and the antiseptic effect of the hops may be preventing rumenitis to prevent the invasion of the portal veins with the *S. necrophorus* organism.

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Thus, the instantly claimed invention would have been no more than a matter of optimization to one of ordinary skill in the art to provide a result effect variable given than the prior art taught that the instantly claimed ingredient of hop acids as well as their corresponding salts not expressly taught by Thompson is well known to be useful in the making of antibacterial pharmaceuticals, like a food product or the animal feed comprising corn, sorghum, wheat or barley and dried brewers yeast containing spent hops taught by Thompson, for oral ingestion by mammals for delivery to the intestine or stomach an effective amount of hop acids because at the time the invention was made it was old and well known in the art that hop acids inhibit undesirable bacteria commonly found in the digestive systems of livestock at a concentration of 1 ppm or greater.

The United States Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicant's inventions differ and, if so, to what extent, from that discussed in the references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to Applicant.

Accordingly, the claimed invention, as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear and convincing evidence to the contrary.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

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identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 6-11 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 of prior U.S. Patent No. 7,090,873 B2 (A*). This is a double patenting rejection.

Claims 1-14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-14 of copending Application No. 10/529,131. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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MCF
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